

Listing of Claims

1-34 (cancelled)

35. (original) A stable pharmaceutical formulation comprising:

- a) a GLP-1 compound selected from the group consisting of: GLP-1, GLP-1 analogs, and GLP-1 derivatives wherein the GLP-1 compound can bind to the GLP-1 receptor;
- b) a tween polymeric surfactant;
- c) a preservative; and
- d) a buffer

wherein the stable formulation is a solution and has a pH between about 6.5 and about 9.0.

36. (original) The formulation of Claim 35, wherein the GLP-1 compound is protected from the activity of dipeptidyl-peptidase IV.

37. (original) The formulation of Claim 35, wherein the GLP-1 compound comprises the sequence of SEQ ID NO:1 or SEQ ID NO:4.

38. (original) The formulation of Claim 36 wherein the GLP-1 compound comprises the sequence of SEQ ID NO:5.

39. (previously presented) The formulation of Claim 35 wherein the GLP-1 compound is GLP-1(7-34), GLP-1(7-35), GLP-1(7-36), GLP-1(7-37), or the amide forms thereof, with at least one modification selected from the group consisting of:

- (a) substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, arginine, or D-lysine for lysine at position 26 and/or position 34 or substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, lysine, or a D-arginine for arginine at position 36;
- (b) substitution of an oxidation-resistant amino acid for tryptophan at position 31;
- (c) substitution according to at least one of:
Y for V at position 16;
K for S at position 18;

- D for E at position 21;
 - S for G at position 22;
 - R for Q at position 23;
 - R for A at position 24; and
 - Q for K at position 26;
 - (d) substitution comprising at least one of:
 - glycine, serine, or cysteine for alanine at position 8;
 - aspartic acid, glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glutamic acid at position 9;
 - serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glycine at position 10; and
 - glutamic acid for aspartic acid at position 15; and
 - (e) substitution of glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine or the D or N-acylated or alkylated form of histidine for histidine at position 7.
40. (original) The formulation of Claim 39, wherein the GLP-1 analog is acylated at an amino acid side group.
41. (original) The formulation of Claim 40, wherein the GLP-1 analog is acylated on the epsilon-amino group of lysine.
42. (original) The formulation of Claim 41, wherein the lysine that is acylated is lysine 34.
43. (original) The formulation of Claim 42, wherein the epsilon-amino group of lysine is acylated with an acyl group selected from the group consisting of C₆-C₁₀ unbranched acyl.
44. (previously presented) The formulation of Claim 35 wherein the GLP-1 compound is a GLP-1 derivative prepared by the process of acylating a GLP-1 analog selected from the group consisting of GLP-1(7-34), GLP-1(7-35), GLP-1(7-36), GLP-1(7-37), and the amide forms thereof, with at least one modification selected from the group consisting of:
- (a) substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, arginine, or D-lysine for lysine at position 26 and/or

- position 34 or substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, lysine, or a D-arginine for arginine at position 36;
- (b) substitution of an oxidation-resistant amino acid for tryptophan at position 31;
- (c) substitution according to at least one of:
Y for V at position 16;
K for S at position 18;
D for E at position 21;
S for G at position 22;
R for Q at position 23;
R for A at position 24; and
Q for K at position 26;
- (d) substitution comprising at least one of:
glycine, serine, or cysteine for alanine at position 8;
aspartic acid, glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glutamic acid at position 9;
serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glycine at position 10; and
glutamic acid for aspartic acid at position 15; and
- (e) substitution of glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine or the D or N-acylated or alkylated form of histidine for histidine at position 7.
45. (original) The formulation of Claim 44 wherein the GLP-1 analog has an arginine substituted for lysine at position 34.
46. (original) The formulation of Claim 45 wherein the GLP-1 analog is acylated on the epsilon-amino group of lysine.
47. (original) The formulation of Claim 35, wherein the GLP-1 compound is a GLP-1 derivative.
48. (original) The formulation of Claim 35 further comprising an isotonicity agent.

- 49. (original) The formulation of Claim 48 wherein the isotonicity agent is glycerin.
- 50. (original) The formulation of Claim 48 wherein the isotonicity agent is sodium chloride.
- 51. (original) The formulation of Claim 35 further wherein the preservative is phenol.
- 52. (original) The formulation of Claim 35 further wherein the preservative is m-cresol.
- 53. (previously presented) A method of treating a person having a condition wherein said condition is characterized by elevated glucose levels, said method comprising administering a pharmacologically effective amount of a formulation of Claim 35.
- 54. (previously presented) The method of claim 53 wherein the condition is Type II diabetes.